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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,012	03/08/2006	Frank Cuttitta	4239-82094-06	4600

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
02/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/571,012	CUTTITTA ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80,81,90-97 and 100-103* is/are pending in the application.

4a) Of the above claim(s) *91-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80,81,90,94-97 and 100-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Final Rejection mailed on 1/5/2011 is hereby vacated and replaced with the current Final Rejection.

Specifically, it was brought to the Examiner's attention on 1/13/2011 that Exhibit was in fact submitted on 12/20/2011, in contrast to the statement made on page 5 of the mailed Final Rejection. Though, the Examiner contends that Exhibit A was not present prior to the mailing of the Final Rejection, this inal rejection is being set forth for the sake of completeness of the record. Specifically, it addresses Applicant's arguments drawn to Exhibit A which were not previously addressed.

Applicant's amendment filed 12/20/2010 have been received and entered into the present application.

As reflected by the attached, completed copy form PTO/SB/08A (one page total), the Examiner has considered the cited references.

Applicant's arguments filed 12/20/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Status of Claims

Claims 80-81, 90-97 and 100-103 are pending.

Claims 91-93 are withdrawn.

Claims 80-81, 90, 94-97 and 100-103 are currently under examination and the subject matter of the present Office Action.

Rejection maintained:

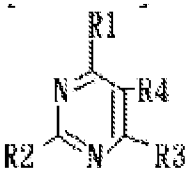
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 80-81, 90, 94-97 and 100-103 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10212235 (original document and translation are attached) as evidenced by the National Cancer Institute (1/28/2005).

JP 10212235 teaches a compound of formula (I) wherein the compound is that of instant claim 80 (paragraph [0064] of translation):



[I]

化合物番号	R1	R2	R3	R4
105	Cl	-NH2	-NHCH2CH2OH	H

Further, it is taught that the compounds of formula (I) is effective for the treatment of tumors, for example, stomach cancer, such as malignant tumor, a benign tumor, and a precancerous change, lung cancer, hepatoma, a pancreatic cancer, colon cancer, a malignant lymphoma, leukemia, a breast

carcinoma, melanoma, renal cancer, brain tumor, peritoneal tumor, spinal cord tumor, hypophyseal tumor, thyroid tumor, laryngeal cancer etc. (paragraph [0035] of translation).

Though JP 10212235 is silent as to the effect of the elected compound to inhibit an activity of a gastrin releasing peptide (GRP), the administration of the claimed compound to patients suffering from cellular proliferative disorders is expected to necessarily have the claimed effect of inhibiting an activity of GRP, whether recognized by the author or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstance or, in the present case, the same host. Please reference MPEP 2112.

Moreover, the very teaching of administering the identical compound to the same patient populations (i.e. patients suffering from cellular proliferative disorders) necessarily means that the claimed inhibition of GRP is necessarily present, whether recognized by the author or not. Further, the treatment of a tumors would necessarily inhibit angiogenesis since angiogenesis is responsible for the progression of the disease (i.e. is angiogenesis mediated), per National Cancer Institute. As stated supra, products of identical composition cannot exert mutually exclusive properties. Please reference MPEP 2112 and Ex parte Novitski, 26 USPQ 1389 (Bd. Pat. App. and Inter 1993).

Response to Applicant's Remarks

Applicant alleges that JP10212235 does not describe the effects of any compound on GRP activity, nor is GRP mentioned in the document. This is not found persuasive. Though JP 10212235 is silent as to the effect of the elected compound to inhibit an activity of a gastrin releasing peptide (GRP), the administration of the claimed compound to patients suffering from cellular proliferative disorders is expected to necessarily have the claimed effect of inhibiting an activity of GRP, whether recognized by the author or not. Products of identical chemical composition cannot exert mutually exclusive properties

when administered under the same circumstance or, in the present case, the same host. Please reference MPEP 2112.

*Applicant alleges that "without any admission to any similarity between Compound 105 and claimed Compound 77427", compound 105 is not among the compounds used in vitro tes*ts of anti-proliferative activity. Firstly, Applicant's statement is not clear. If Applicant does not believe that compound 105 of JP 10212235 is the instantly elected compound, Applicant is invited to set forth reasons and evidence. Further, JP 10212235 clearly states that compounds of formula (I), including the elected compound, are useful for the treatment of tumors, for example, stomach cancer, such as malignant tumor, a benign tumor, and a precancerous change, lung cancer, hepatoma, a pancreatic cancer, colon cancer, a malignant lymphoma, leukemia, a breast carcinoma, melanoma, renal cancer, brain tumor, peritoneal tumor, spinal cord tumor, hypophyseal tumor, thyroid tumor, laryngeal cancer etc. (paragraph [0035] of translation).

Applicant alleges that Tables 27-31 does not show an anti-proliferative effect on every compound against every cell line tested. This is not found persuasive. It appears from this statement that Applicant infers requirement of testing "every cell line." Applicant is reminded that as stated in the Final Rejection mailed on 6/10/2010 the instant specification merely teaches proliferation assay of lung cancer cell line H1299 with administration of the elected compound as well as xenograft lung cancer model (Examples 8 and 9, pages 36-37). Therefore, it seems that Applicant is arguing against the enablement of their own invention.

Applicant alleges that the omissions in some of the tables demonstrate considerable variability among the biological effects of the tested compounds. It is not clear how Applicant has reached this conclusion. Applicant fails to advanced any specific reasons or evidence, aside from Counsel's own allegation, in support of this position that no motivation exists in the present obviousness rejection. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record.

Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP 2145, which states "The arguments of counsel cannot take the place of evidence in the record."

Applicant has set forth Exhibit A in support that the compounds used in the experiments of *JP10212235 differ structurally from compound 105. Therefore, given the "structural differences" one of* skill would not necessarily infer a biological property of compound 105. This is not found persuasive. Firstly, it should be noted that JP10212235 specifically states that the compounds of formula (I), including the elected compound, are useful for the treatment of tumors, for example, stomach cancer, such as a malignant tumor, a benign tumor, and a precancerous change, lung cancer, hepatoma, pancreatic cancer, colon cancer, malignant lymphoma, leukemia, breast carcinoma, melanoma, renal cancer, brain tumor, peritoneal tumor, spinal cord tumor, hypophyseal tumor, thyroid tumor, laryngeal cancer (paragraph [0035] of translation). With regard to the Exhibit A, it should be noted that it only exhibits a few of the one hundred and thirty one compounds tested (pages 13 to 36 of the translation). Therefore, the list set forth by Applicant is not representative of the compounds actually tested by the reference. Arguendo the above, Applicant has not set forth any reasoning or evidence as to what these "structural differences" are and why they do not necessarily infer a "biological property." Applicant fails to advanced any specific reasons or evidence, aside from Counsel's own allegation, in support of this position that no motivation exists in the present obviousness rejection. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP 2145, which states "The arguments of counsel cannot take the place of evidence in the record."

Conclusion

No claim is found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628